REMARKS

The final office action of December 7, 2006 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 22-25, 28-30, and 35-44 remain in this case, claims 23-25 being amended, claims 31-34 being cancelled, and claims 37-44 being added by the present response. No new matter has been added. Specifically:

The amendment to the specification is supported by the abstract and column 7, line 66 to column 8, line 34 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed.

In claim 25, "aerosol parameters" is supported by claim 1 as filed; the language of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" is supported by page 2, lines 27-28 and page 3, lines 32-34 of the application as filed, column 8, lines 21-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

Claim 37 is supported by column 8, line 21 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

Claim 38 is supported by claim 10 as filed.

Claim 39 is supported by column 8, lines 20-21 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

Claim 40 is supported by column 8, lines 1-10 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

Claim 41 is supported by column 8, lines 7-8 and 22-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

Claim 42 is supported by column 7, lines 16-18 and column 8, lines 29-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended.

In claim 43, inputting individual parameters is supported by claim 6 as filed; inserting a memory medium is supported by page 3, lines 12-13 of the application as filed; storing individual patient parameters on the memory medium is supported by claim 7 as filed; the language of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" is supported by page 2, lines 27-28 and page 3, lines 32-34 of the application as filed, column 8, lines 21-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended; adjusting individual doses is supported by page 3, lines 24-26 of the application as filed; evaluating the patient parameters is supported by claim 10 as filed; adjusting a respiratory flow or tidal volume is supported by claim 10 as filed.

In claim 44, inputting individual parameters is supported by claim 6 as filed; inserting a memory medium is supported by page 3, lines 12-13 of the application as filed; storing aerosol parameters on the memory medium is supported by claim 7 as filed;; the language of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" is supported by page 2, lines 27-28 and page 3, lines 32-34 of the application as filed, column 8, lines 21-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as currently amended; adjusting individual doses is supported by page 3, lines 24-26 of the application as filed; evaluating the aerosol parameters is supported by claim 10 as filed; adjusting a respiratory flow or tidal volume is supported by claim 10 as filed.

Rejection under 35 U.S.C. §102

Claims 22, 25, 28-32, and 35-36 were rejected under 35 U.S.C. 102(b) as being anticipated by Goodman (5,813,397). Applicant respectfully disagrees with the rejection.

> "Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in prior pleaded art,

there is no anticipation." *Stauffer v. Slenderella Systems of California, Inc.*, 254 F.2d 127, 115 USPQ 347 (9th Cir. 1957).

Amended independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising ... controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" [emphasis added].

Goodman discloses an MDI (metered dose inhaler) which monitors breathing maneuvers. The MDI in Goodman is a manually triggered conventional inhalation device. Goodman only discloses measuring the breathing maneuvers and administering drug based on the measured breathing maneuvers. Goodman does not disclose controlling the air flow through the inhalation device or adjusting the air flow. Goodman only discloses adjusting the drug administration based on the measured air flow.

In contrast, in the present invention as claimed in claim 25, during the breathing maneuver, the air flow is controlled and adjusted by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed. Goodman does not disclose controlling an air flow through the inhalation device.

Independent claim 25 also claims, in part, "adjusting at least one breathing parameter of the inhalation device based on the inhalation parameters; wherein the breathing parameter is selected from the group consisting of: a) a respiratory flow; b) a tidal volume; and c) a combination of a) and b)" and "wherein the inhalation parameters are selected from the group consisting of: a) a plurality of individual patient parameters for the patient; b) a plurality of aerosol parameters; and c) a combination of a) and b)".

The Examiner states that Goodman "has the capability to detect changes ... including flow rate and tidal volumes and adjust these parameters" [page 2, lines 22-24, present office action, dated 12-07-06] but does not indicate where this is disclosed in the patent. Goodman does not disclose adjusting flow rate or tidal volume using individual patient parameters or aerosol parameters.

Tidal volume is the volume of air inhaled and exhaled with each breath. Tidal volume and respiratory flow both relate to air entering and leaving a patient's lungs during a breath. Goodman discloses that "the selected particle size can then be used with an optimal inspiratory flow, inspiratory pause, expiratory flow, and tidal volume to deliver the aerosol medication to the most therapeutically efficacious locations in the patient's airway" (column 34, lines 41-45, U.S. 5,813,397). Goodman discloses adjusting aerosol delivery based on inspiratory flow, pause, expiratory flow, and tidal volume. Goodman further discloses: "It is another object of the invention to deliver aerosolized compounds in response to a measure of a patient's breathing pattern during inspiration. It is another object to select the optimal point or points for release of one or more pulses of medication based on an analysis of the patient's inspiratory flow in a first detected flow and to release the medication on the occurrence of the determined point or points during a subsequently detected inspiratory breath" (column 5, lines 17-24, U.S. 5,813,397). Goodman discloses only measuring, analyzing, and detecting respiratory flow and adjusting aerosol delivering based on measured respiratory flow. Goodman does not disclose adjusting respiratory flow or tidal volume and does not disclose adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Goodman does not disclose each and every element of Applicant's claim 25. Therefore, it is respectfully suggested that the rejection of independent claim 25 as being anticipated by Goodman is overcome. Claims 22, 28-31, and 35-36, as well as new claim 37-42, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection of claims 22, 25, 28-31, and 35-36 is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 23, 24, 33, and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Wallace (6,024,089).

Applicants respectfully disagree, and believe the claims, as amended, are patentable over Goodman for the reasons given above in respect to the section 102 rejection of claim 25, from which claims 23, 24, 33, and 34 depend. The argument above as to the novelty of claim 25 is repeated here by reference.

The basic considerations which apply to obviousness rejections under MPEP Section 2141 are:

(1) the claimed invention must be considered as a whole;

(2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(4) reasonable expectation of success is the standard by which obviousness is determined.

Amended independent claim 25, upon which claims 23, 24, 33, and 34 depend, claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising ... controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" [emphasis added].

Goodman teaches an MDI (metered dose inhaler) which monitors breathing maneuvers. The MDI in Goodman is a manually triggered conventional inhalation device. Goodman only teaches measuring the breathing maneuvers and administering drug based on the measured breathing maneuvers. Goodman does not teach or suggest controlling the air flow through the inhalation device or adjusting the air flow. Goodman only teaches adjusting the drug administration based on the measured air flow.

In contrast, in the present invention as claimed in claim 25, during the breathing maneuver, the air flow is controlled and adjusted by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed. Goodman does not teach or suggest controlling an air flow through the inhalation device.

Wallace does not provide what Goodman lacks. Wallace teaches a ventilation control system for controlling the ventilation of a patient. In contrast to the method of claim 25 for an inhalation device, where the patient provides the breathing force, ventilators actively provide the force to provide air or oxygen to the patient lungs, when the patient otherwise is unable to

breathe unassisted. Wallace does not teach or suggest controlling an air flow through an inhalation device.

Independent claim 25 also claims, in part, "adjusting at least one breathing parameter of the inhalation device based on the inhalation parameters; wherein the breathing parameter is selected from the group consisting of: a) a respiratory flow; b) a tidal volume; and c) a combination of a) and b)" and "wherein the inhalation parameters are selected from the group consisting of: a) a plurality of individual patient parameters for the patient; b) a plurality of aerosol parameters; and c) a combination of a) and b)".

The Examiner states that Goodman "has the capability to detect changes ... including flow rate and tidal volumes and adjust these parameters" [page 2, lines 22-24, present office action, dated 12-07-06, emphasis added] but does not indicate where this is taught or suggested in the patent. Goodman only teaches measuring flow rate and does not teach or suggest adjusting flow rate or tidal volume using individual patient parameters or aerosol parameters.

Goodman teaches that "the selected particle size can then be used with an optimal inspiratory flow, inspiratory pause, expiratory flow, and tidal volume to deliver the aerosol medication to the most therapeutically efficacious locations in the patient's airway" (column 34, lines 41-45, U.S. 5,813,397). Goodman teaches adjusting aerosol delivery based on inspiratory flow, pause, expiratory flow, and tidal volume. Goodman further teaches: "It is another object of the invention to deliver aerosolized compounds in response to a measure of a patient's breathing pattern during inspiration. It is another object to select the optimal point or points for release of one or more pulses of medication based on an analysis of the patient's inspiratory flow in a first detected flow and to release the medication on the occurrence of the determined point or points during a subsequently detected inspiratory breath" (column 5, lines 17-24, U.S. 5,813,397). Goodman teaches only measuring, analyzing, and detecting respiratory flow and adjusting aerosol delivering based on measured respiratory flow. Goodman does not teach or suggest adjusting respiratory flow or tidal volume and does not teach or suggest adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Wallace does not provide what Goodman lacks. Wallace teaches to "start up the ventilator using a predetermined set of ventilator control settings deemed to be safe for the

widest possible variety of patients" (U.S. Patent No. 6,024,089, column 3, lines 26-29, emphasis added). Wallace teaches using ventilator settings safest for the most possible patient rather than any patient-specific settings. Wallace does not teach or suggest adjusting respiratory flow or tidal volume and does not teach or suggest adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Furthermore, there is no motivation to combine Goodman's inhaler with Wallace's ventilator, nor would the combination teach or suggest the present invention. Inhalers and ventilators are very different devices with different functions. A person of ordinary skill in the art of inhalers would not combine elements from ventilator art with elements of an inhaler.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Goodman in view of Wallace. Claims 23-24 and 33-34, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22, 24, 25, 28-32, 34, and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore *et al.* (5,931,160) in view of Rapoport *et al.* (5,490,502).

Amended independent claim 25, upon which claims 23, 24, 33, and 34 depend, claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising ... controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" [emphasis added].

Gilmore teaches a ventilation control system for controlling the ventilation of a patient. In contrast to the method of claim 25 for an inhalation device, where the patient provides the breathing force, ventilators actively provide the force to provide air or oxygen to the patient lungs, when the patient otherwise is unable to breathe unassisted. Gilmore does not teach or suggest controlling an air flow through an inhalation device.

Rapoport does not provide what Gilmore lacks. Rapoport relates to a completely different field from the present invention. Rapoport teaches adjusting the positive airway pressure of a

patient to an optimum value in the treatment of obstructive sleep apnea. The treatment of sleep apnea, i.e. the intermittent obstruction of the upper airway occurring during sleep, is in no way linked to the administering of a controlled inhalation of therapeutic aerosol for a patient during breathing maneuvers according to claim 25. Rapoport teaches basically using only two different pressures such that aerosol administration is not possible, because at the beginning of the inhalation a high flow, which decreases quickly, is present. Therefore, a large amount of drug would be applied to the throat but would not reach the lung. Rapoport does not teach or suggest controlling an air flow through an inhalation device.

Independent claim 25 also claims, in part, "adjusting at least one breathing parameter of the inhalation device based on the inhalation parameters; wherein the breathing parameter is selected from the group consisting of: a) a respiratory flow; b) a tidal volume; and c) a combination of a) and b)" and "wherein the inhalation parameters are selected from the group consisting of: a) a plurality of individual patient parameters for the patient; b) a plurality of aerosol parameters; and c) a combination of a) and b)".

Gilmore teaches a ventilation control system for controlling the ventilation of a patient. Gilmore does not teach or suggest adjusting respiratory flow or tidal volume of an inhalation device and does not teach or suggest adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Rapoport does not provide what Gilmore lacks. Rapoport teaches adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea. Rapoport does not teach or suggest adjusting respiratory flow or tidal volume of an inhalation device and does not teach or suggest adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Furthermore, there is no motivation to combine Gilmore's ventilator with Rapoport's sleep apnea breathing device, nor would the combination teach or suggest the present invention. Neither Gilmore nor Rapoport teach a method using an inhalation device. Each of the references teaches very different devices that perform different functions. A person of ordinary skill in the art of inhalers would not combine elements from ventilator or sleep apnea device art with elements of an inhaler.

Gilmore and Rapoport, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully suggested that the rejection of independent claim 25 as being obvious over Gilmore in view of Rapoport is overcome. Claims 22, 24, 28-32, 34, and 35, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 23 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore *et al.* (5,931,160) in view of Rapoport *et al.* (5,490,502) and further in view of Goodman (5,813,397).

Applicants respectfully disagree, and believe the claims, as amended, are patentable over Gilmore in view of Rapoport for the reasons given above in respect to the section 103 rejection of claim 25, from which claims 23 and 33 depend. The argument above as to the non-obviousness of claim 25 is repeated here by reference.

Amended independent claim 25, upon which claims 23, 24, 33, and 34 depend, claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising ... controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" [emphasis added].

Goodman does not provide what Gilmore and Rapoport lack. Goodman teaches an MDI (metered dose inhaler) which monitors breathing maneuvers. The MDI in Goodman is a manually triggered conventional inhalation device. Goodman only teaches measuring the breathing maneuvers and administering drug based on the measured breathing maneuvers. Goodman does not teach or suggest controlling the air flow through the inhalation device or adjusting the air flow. Goodman only teaches adjusting the drug administration based on the measured air flow.

In contrast, in the present invention as claimed in claim 25, during the breathing maneuver, the air flow is controlled and adjusted by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual

inhalation maneuver, which guarantees that the entire inhalation is successfully completed. Goodman does not teach or suggest controlling an air flow through the inhalation device.

Independent claim 25 also claims, in part, "adjusting at least one breathing parameter of the inhalation device based on the inhalation parameters; wherein the breathing parameter is selected from the group consisting of: a) a respiratory flow; b) a tidal volume; and c) a combination of a) and b)" and "wherein the inhalation parameters are selected from the group consisting of: a) a plurality of individual patient parameters for the patient; b) a plurality of aerosol parameters; and c) a combination of a) and b)".

Goodman does not provide what Gilmore and Rapoport lack. The Examiner states that Goodman "has the capability to detect changes ... including flow rate and tidal volumes and adjust these parameters" [page 2, lines 22-24, present office action, dated 12-07-06] but does not indicate where this is taught or suggested in the patent. Goodman only teaches measuring flow rate and does not teach or suggest adjusting flow rate or tidal volume using individual patient parameters or aerosol parameters.

Goodman teaches that "the selected particle size can then be used with an optimal inspiratory flow, inspiratory pause, expiratory flow, and tidal volume to deliver the aerosol medication to the most therapeutically efficacious locations in the patient's airway" (column 34, lines 41-45, U.S. 5,813,397). Goodman teaches adjusting aerosol delivery based on inspiratory flow, pause, expiratory flow, and tidal volume. Goodman further teaches: "It is another object of the invention to deliver aerosolized compounds in response to a measure of a patient's breathing pattern during inspiration. It is another object to select the optimal point or points for release of one or more pulses of medication based on an analysis of the patient's inspiratory flow in a first detected flow and to release the medication on the occurrence of the determined point or points during a subsequently detected inspiratory breath" (column 5, lines 17-24, U.S. 5,813,397). Goodman teaches only measuring, analyzing, and detecting respiratory flow and adjusting aerosol delivering based on measured respiratory flow. Goodman does not teach or suggest adjusting respiratory flow or tidal volume and does not teach or suggest adjusting respiratory flow or tidal volume based on individual patient parameters for the patient or aerosol parameters.

Furthermore, there is no motivation to combine Gilmore's ventilator with Rapoport's sleep apnea breathing device and Goodman's inhaler, nor would the combination teach or suggest the present invention. A sleep apnea breathing and a ventilator are both very different devices than an inhaler, and each device performs a different function. A person of ordinary skill in the art of inhalers would not combine elements from ventilator or sleep apnea device art with elements of an inhaler.

Gilmore, Rapoport, and Goodman, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Gilmore in view of Rapoport and further in view of Goodman. Claims 23 and 33, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

To further prosecution, the Applicant respectfully submits that new independent claims 43 and 44 include the language "method for administering a controlled inhalation of therapeutic aerosols ... comprising ... controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" and adjusting at least one breathing parameter of the inhalation device based on the individual patent parameters [claim 43] or aerosol parameters [claim 44]; wherein the breathing parameter is selected from the group consisting of: a) a respiratory flow; b) a tidal volume; and c) a combination of a) and b)" and should therefore be allowable for the same reasons claim 25 is allowable.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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